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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,518

07/18/2005

Brian Philip Allen

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

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EXAMINER

SALZMAN, KOURTNEY R

ART UNIT

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1795

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,518	Applicant(s) ALLEN ET AL.	
	Examiner KOURTNEY R. SALZMAN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>July 18, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the first office action on the merits for application 10/519,518 filed July 18, 2005. This is the 371 national stage application for PCT/GB03/02756 filed June 27, 2003.
2. Claims 33-64 are currently pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 33-38, 43, 44, 50, 51, 53, 57, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by ROBERTS et al (WO 00/22158).

Regarding claim 33, ROBERTS et al teaches a P450 cytochrome attached to a gold electrode on page 4, full paragraphs 2-3.

Regarding claims 34-36, ROBERTS et al teaches, from the bottom of page 3 to the bottom of page 4, a series of covalent and non-covalent methods of linking,

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including the addition of chemical groups like Aldrithiol for immobilization of the enzyme on the surface of the electrode.

Regarding claims 37 and 38, ROBERTS teaches, in the third full paragraph of page 4, the use of a gold electrode coated in an Aldrithiol compound for interaction of immobilization of the enzyme.

Regarding claims 43 and 44, ROBERTS et al teaches the use of a lipid film directly immobilizing the enzyme on the surface at the top of page 3.

Regarding claims 50, 51 and 53, ROBERTS et al teaches, from the bottom of page 3 to the bottom of page 4, a series of covalent and non-covalent methods of linking, including the addition of chemical groups like Aldrithiol for immobilization of the enzyme on the surface of the electrode.

Regarding claim 57, at the top of page 5, ROBERTS et al teaches the use of at least a two electrode system.

Regarding claims 61 and 62, ROBERTS et al teaches a method for the study of a therapeutic agent or candidate drug, an example assay, to determine the metabolism of the drug in the first full paragraph of page 2. ROBERTS et al teaches a P450 cytochrome attached to a gold, metal electrode on page 4, full

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paragraphs 2-3. The bottom of page 10 to the top of page 11 teaches scanning the voltage supplied to the DME for the assay reading to determine the rate of metabolizing.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 39-42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROBERTS et al (WO 00/22158), in view of SCHUHMANN (Schuhmann, W., "Amperometric Enzyme Biosensors Based on Optimized Electron-transfer Pathways and Non-manual Immobilisation Procedures," Journal of Biotechnology, 82(4):425-41, February 2002.).

ROBERTS et al teaches the immobilization of the enzyme on the electrode, as shown in pages 3 and 4. ROBERTS et al fails to teach the use of hydrogels for immobilization.

Regarding claims 39-42 and 46, SCHUHMANN teaches a gold electrode with numerous immobilization options including the immobilization of groups with different surface charges and/or functionalities in the first column of page 430 and the use of hydrogels in the abstract and on pages 433 and 434. The second column of page 430 discusses the individual combinations of surfaces charges causing offshoots with different known chemical compounds to also be obvious.

At the time of the invention, it would have been obvious to immobilize an enzyme on an electrode, as discussed in ROBERTS et al, in the method of SCHUHMANN because the method of SCHUHMANN allows for the exploitation and optimization of the surface of the enzyme and electrode for conditions most desirable for each assay. Furthermore, it would have been obvious to substitute a hydrogel or any other known immobilization technique in the immobilization of the enzyme on the electrode, as in SCHUHMANN or ROBERTS et al because immobilization techniques would clearly render the same predictable result of immobilization.

9. Claims 45 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROBERTS et al (WO 00/22158), in view of SUGIHARA et al (Sugihara, N, et al, "Immobilization of Cytochrome P-450 and Electrochemical Control of its Activity", Polym. Adv. Technol., 9:307-313, 1998.).

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ROBERTS et al teaches the immobilization of the enzyme on the electrode, as shown in pages 3 and 4. ROBERTS et al fails to teach the use of a delocalized electron system for immobilization.

Regarding claims 45 and 52, SUGIHARA et al teaches the immobilization of the enzyme by utilizing a delocalized electron system and discussed in the second paragraph of the Introduction.

At the time of the invention, it would have been obvious to immobilize an enzyme on an electrode, as discussed in ROBERTS et al, in the method of SUGIHARA et al because the substitution of a known immobilization technique for attaching an enzyme to an electrode for another would clearly render the same predictable result of immobilization.

10. Claims 47-49 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROBERTS et al (WO 00/22158), in view of MURRAY (Murray, R., "Chemically Modified Electrodes," Acc. Chem. Res., 13:135-141, 1980.).

ROBERTS et al discloses the use of mediators and the chemical mediators to include those listed by MURRAY, as incorporated as a reference in its entirety at the bottom of page 4.

Regarding claims 47-49 and 54-56, MURRAY et al teaches the use of ferrocenes and quinones in the section "Immobilized Electron-Transfer Couples Swapping

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Electrons with the Electrode” on pages 138-139. The specific ferrocene shown in claim 49 is obvious in view of the discussion of ferrocene characteristics of MURRAY and in view of the chemical basis of the claim.

At the time of the invention, it would have been obvious to immobilize an enzyme on an electrode, as discussed in ROBERTS et al, using the methods discussed in MURRAY because it is the substitution of one known method of immobilization for another, clearly rendering the same predictable result of immobilization.

11. Claims 58-60, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROBERTS et al (WO 00/22158).

Regarding claim 58, ROBERTS et al teaches many methods immobilization and a three electrode system between pages 3 and 5. ROBERTS et al fails to explicitly teach the immobilization of different enzymes on each electrode. However, it would have been obvious to immobilize any number of different enzymes on different electrodes in order to test each enzymes reaction to any given sample.

Regarding claim 59, ROBERTS et al teaches many methods immobilization and a three electrode system between pages 3 and 5. It would have been obvious to have a DME immobilized on another electrode as taught in claim 50 because simple replication of an electrode is obvious.

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Regarding claim 60, ROBERTS et al fails to explicitly teach the immobilization of different enzymes on each electrode. However, it would have been obvious to immobilize any number of different enzymes on different electrodes in order to test each enzymes reaction to any given sample.

Regarding claims 63 and 64, ROBERTS et al teaches a method for the study of a therapeutic agent or candidate drug, an example assay, to determine the metabolism of the drug in the first full paragraph of page 2. ROBERTS et al teaches a P450 cytochrome attached to a gold, metal electrode on page 4, full paragraphs 2-3. The bottom of page 10 to the top of page 11 teaches scanning the voltage supplied to the DME for the assay reading to determine the rate of metabolizing. It would be obvious to one of skill in the art to choose a covalent or noncovalent addition which would allow for a rate that is at least as fast as a rate of consumption of electrons by the DME in order for the assay to function successfully. Through optimization of the process and undue experimentation within the electrode and chemical group additive, the correct and most efficient combination can be found, something unique to the chemical group, electrode and enzyme.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is

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(571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kaj K Olsen/
Primary Examiner, Art Unit 1795